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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,886	12/01/2005	Jacques Thilly	B45319	2976
24197	7590	12/19/2008		
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER SMALLEY, JAMES N	
			ART UNIT 3781	PAPER NUMBER
			MAIL DATE 12/19/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,886	Applicant(s) THILLY ET AL.	
	Examiner JAMES N. SMALLEY	Art Unit 3781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6 and 8-15 is/are rejected.
- 7) ☒ Claim(s) 3,4,7 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/16/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-2, 9-12, 14-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Amschlenger et al. WO 01/60699.

Examiner notes reference is made to Amschlenger et al. US 6,868,978 for an English translation.

Amschlenger '978 teaches an elastomer closure part (14), a clamp part (3), a cover part (2) comprising a segment (defined by weakend lines (I) and hinge (34)) attached by a frangible link (I), a sealing ridge (21). The segment is sufficiently detached from the remainder of the cover to allow the cover to be removed. This removal of the cover, after tearing and pulling, is read to be the "thereby allow access" in the second to last line of claim 1. In other words, the claim is broadly worded such that the cover need not remain on the vial in order for the claim limitation to be met.

Regarding claim 9, the reference teaches "plastically deformable aluminum" in column 3, line 19, which is read to comprise "moldable plastics material" as metal is known to have a plastic range.

Regarding claim 11, the connection between the connection between flange (3') and container rim (7) is read to be a snap fit, as the metal could snap over the annular rim (7).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amschlinger et al. WO 01/60699 in view of Burns US 5,699,923.

Amschlinger '978 teaches all limitations substantially as claimed, but fails to teach the closure part being upwardly convex.

Burns '923 teaches it is known to form closure parts upwardly convex, such as in figure 11, and teaches, in column 6, lines 43-48, that the benefit therein is to direct a bodily fluid away from the center of the sealing element.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the closure part of Amschlinger '978, forming it to be upwardly convex as taught by Burns '923, motivated by the benefit of directing fluids away from the center. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Regarding claim 6, the clamp part has an opening therein (22), through which the convex portion would inherently bulge. The snap-fit is read to be the curl (3') of the clamping part, which snaps over the vial rim (4), as shown in figure 6 for example.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amschlinger et al. WO 01/60699.

Amschlinger '978 teaches all limitations substantially as claimed, but fails to teach the upper part being formed of a thermoplastic elastomer. The reference simply teaches plastic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the cover of a thermoplastic elastomer motivated by the benefit of forming it from a ductile resilient and inexpensive material. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amschlinger et al. WO 01/60699 in view of Py US 6,604,561.

Amschlinger '978 teaches all limitations substantially as claimed, but fails to teach filling the container with a needle piercing the stopper, and then sealing the opening with residual heat.

Py '561 teaches a method of filling a vial with a medication, in which a needle pierces a stopper, and then such opening is sealed upon removal of the needle with residual heat. In column 3, lines 19-28, the reference teaches the method is more sanitary, as the filling occurs after sealing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of filling the container of Amschlinger '978, filling the container with a needle piercing the stopper, and then sealing the opening with residual heat, as taught by Py '561, motivated by the benefit of maintaining a higher level of sterility.

Allowable Subject Matter

7. Claims 3-4, 7, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES N. SMALLEY whose telephone number is (571)272-4547. The examiner can normally be reached on Monday - Friday 10 am - 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Stashick can be reached on (571) 272-4561. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James N Smalley/
Examiner, Art Unit 3781

/Anthony D Stashick/
Anthony D Stashick
Supervisory Patent Examiner, Art Unit 3781